K073314

V. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 21 2008

Submitter

Name:.....Heany Industries Inc.
Street:.....249 Briarwood Lane
City:.....Scottsville
State:.....NY
Zip-Code:.....14546
Country:.....USA
Contact:.....Corey Dunn
Ceramic Engineer
Phone:.....585-889-2700
Fax:.....585-889-2708
E-mail:.....coreyd@heany.com

Date:.....11/16/07

Name of Device

Proprietary Name:.....Heany Industries Inc. Dental Zirconia
Classification Name:.....Porcelain powder for clinical use
Common Name:.....All-ceramic core material

Predicate Devices

Foundation Milling Center Z-Blocks.....K062389 (Foundation Milling Center (FMC)

LAVA™ Frame:.....K011394 (3M ESPE AG)

IPS E.MAX CAD/IPS E.MAX ZIRCAD...K051705 (Ivoclar Vivadent, Inc.)

Description for the Premarket Notification

Heany Industries Inc. Dental Zirconia is an all ceramic core material made of zirconium oxide. It is provided as a block or disk shape. CAD/CAM fabrication of core material can then be used to produce copings and or substrates for fixed all ceramic dental restorations above the gum line. The material is used for the manufacturing of inlays, onlays, veneers, crowns and bridges. The material is then fired in an oven to harden the ZrO_2. The milling and final oven hardening is completed by the customer.

The technological characteristics between the predicate and proposed devices are identical. All chemical ingredients for the proposed device are already contained in the predicate devices. Biocompatibility, physical and mechanical properties have been tested to show Heany Industries Inc. Dental Zirconia is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Mr. Corey Dunn
Ceramic Engineer
Heany Industries Incorporated
249 Briarwood Lane
Scottsville, New York 14546

Re: K073314
Trade/Device Name: Heany Industries Incorporated Dental Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 20, 2007
Received: November 26, 2007

Dear Mr. Dunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

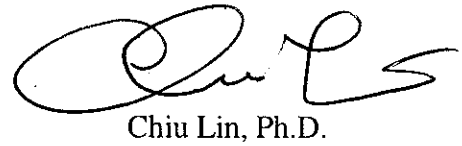
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K073314

Device Name: Heany Industries Inc. Dental Zirconia

Indications for Use:

Heany Industries Inc. Dental Zirconia is non implantable material intended for CAD/CAM fabrication of core material used in all-ceramic dental restorations. The material is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

Prescription Use ___X____
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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